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## Food and Drug Administration

**[Docket No. 98 F-0183]**

**AGENCY:** Food and Drug Administration, HHS.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 2-hydroxy-1-[4-(2-hydroxyethoxy)phenyl]-2-methyl-1-propanone as a photoinitiator for adhesives and pressure-sensitive adhesives intended for use in food-contact applications. This action responds to a petition filed by Ciba Specialty Chemicals Corp.

**DATES:** This regulation is effective *(insert date of publication in the Federal Register)*. Submit written objections and requests for a hearing by *(insert date 30 days after date of publication in the Federal Register)*.

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, **rm.** 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 20241 8-3081 ,

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 31, 1998 (63 FR 15425), FDA announced that a food additive petition (FAP 8B4589) had been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., Tarrytown, NY 1059 1-9005. The petition proposes to amend the food additive regulations to provide for the safe use of 2-hydroxy-1-[4-

(2-hydroxyethoxy)phenyl]-2-methyl-1-propanone as a photoinitiator for adhesives complying with §175.105 *Adhesives* (21 CFR 175.105) and pressure-sensitive adhesives complying with §175.125 *Pressure-sensitive adhesives* (21 CFR 175.125) intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in §§ 175.105 and 175.125 should be amended as set forth below.

In accordance with §171.1 (h) (21 CFR 171.1 (h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (address above) by appointment with the information contact person listed above. **As** provided in § 171.1 (h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 8B4589 (63 FR 15425). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at anytime on or before *(insert date 30 days after date of publication in the Federal Register)*, file with the Dockets Management Branch (address above) written objection thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each

numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objection received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

#### **List of Subjects in 21 CFR Part 175**

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 175 is amended as follows:

#### **PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS**

1. The authority citation for 21 CFR part 175 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342.348, 379e.

2. Section 175.105 is amended in the table in paragraph (c)(5) by alphabetically adding an entry under the headings “Substances” and “Limitations” to read as follows:

#### **3175.105 Adhesives.**

\* \* \* \*

( C ) \* \* \*

( 5 ) \* \* \*

Substances	Limitations
2-Hydroxy-1-[4-(2-hydroxyethoxy)phenyl]-2-methyl-propanone (CAS Reg. No. 106797-53-9),	For use only as a photoinitiator at a level not to exceed 5 percent by weight of the adhesive.

3. Section 175.125 is amended by adding paragraph (a)(8) and by revising paragraph (b)(1) to read as follows:

**\$175.125 Pressure-sensitive adhesives.**

\* \* \* \*

(a) \* \* \*

(8) 2-Hydroxy-1-[4-(2-hydroxyethoxy)phenyl]-2-methyl-1-propanone (CAS Reg. No. 106797-53-9) as a photoinitiator at a level not to exceed 5 percent by weight of the pressure-sensitive adhesive.

(b) \* \* \*

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(1) Substances listed in paragraphs (a)(1), (a)(2), (a)(3), (a)(5), (a)(6), (a)(?), and (a)(8) of this section, and those substances prescribed by paragraph (a)(4) of this section that are not identified in paragraph (b)(2) of this section. <sup>BB</sup> 9-22-98

\* \* \* \* \*

Dated: 9/15/98 - - - - -

SEP 15 1998

L. Robert Lake

L. Robert Lake  
Director, Office of Policy, Planning and Strategic  
Initiatives, Center for Food Safety and Applied Nutrition

[FR Dec. 98-???? Filed ?-?-?-98; 8:45 am]

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Jen Windsor